NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TARO PHARMACEUTICAL INDUSTRIES LTD., TARO PHARMACEUTICALS NORTH AMERICA, INC., and TARO PHARMACEUTICALS U.S.A., INC. Plaintiffs, v. NOVITIUM PHARMA, LLC, Defendant.	Civ. Action No. 19-01028 (FLW) **OPINION**

WOLFSON, Chief Judge:

In this claim construction Opinion, the Court construes disputed claim terms in a family of four U.S. Patents which are directed toward manufacturing processes and compositions of a highly pure and stable form of malathion, a pharmaceutical active ingredient used to treat lice and their eggs. After reviewing the parties' briefings and exhibits, and holding a *Markman* hearing, the Court construes the disputed claim terms in accordance with the intrinsic and extrinsic evidence, as set forth herein.

I. BACKGROUND

Plaintiffs Taro Pharmaceutical Industries Ltd., Taro Pharmaceuticals North America, Inc., and Taro Pharmaceuticals U.S.A., Inc. ("Taro") (collectively, "Plaintiffs") brought the instant patent infringement suit against Defendant Novitium Pharmaceutical, LLC ("Novitium") ("Defendant"), through a Complaint filed on January 24, 2019. At issue in this claim construction dispute are four patents owned by Taro which share a common specification: U.S. Patent Nos. 7,560,445 ("the '455 patent"), 7,977,324 ("the '324 patent"), 8,039,657 ("the '657

patent"), and 8,536,155 ("the '155 patent") (collectively, the "patents-in-suit"). Pls. Opening Br. 1. The patents-in-suit are directed to manufacturing processes and compositions of a highly pure and stable form of malathion, an insecticide used to treat head lice and their eggs. *Id.* Specifically, the patents-in-suit teach manufacturing techniques that generate significantly lower levels of toxic byproducts. *E.g.*, '445 Patent at 2:58-3:3. Taro currently markets formulations utilizing embodiments of the patents-in-suit in a topical 0.5% malathion lotion under the OVIDE® brand name. Pls. Opening Br. 1.

The instant litigation arises because Novitium filed an Abbreviated New Drug Application ("ANDA") with the FDA to market a generic 0.5% malathion product. *Id.* In response, Taro filed the present infringement suit under the Hatch-Waxman Act. *Id.* Taro alleges that Novitium's generic product has or will infringe certain composition and process claims of the patents-in-suit. *Id.* In response, Novitium has asserted that the patents-in-suit are not infringed, and has advanced invalidity theories for each of the asserted claims. *Id.*

The parties dispute seven claim terms contained within the patents-in-suit. Two of the disputed claims—those related to "assaying the malathion"—are construed together, as both turn on the same evidence, which considers whether the techniques used to assay malathion are limited to those specifically listed in the intrinsic evidence. Both parties aver that their constructions are in line with the plain and ordinary meaning, except for the "20% sodium bisulfite solution," which Defendant contends is indefinite and invalid. The chart below provides a summary of the disputed claim terms, and the parties' respective proposed construction for each term.

Disputed Term	Patents / Claims	Taro's Construction	Novitium's Construction
"wherein the sulfur reagent is sodium bisulfite"	'445 patent, claim 7; '657 patent, claim 15	"wherein the sulfur reagent is an aqueous solution of sodium bisulfite"	"wherein the sulfur reagent is an aqueous solution prepared from the chemical compound $NaHO_3$"
"20% sodium bisulfite solution"	'445 patent, claims 8, 49, and 50; '657 patent, claims 16, 17, and 23	"a solution that includes 20% (w/w) sodium bisulfite"	Indefinite.
"malathion carboxylic acid[s]"	'445 patent, claims 1, 11, 12, 32, 33, 34, 53, 54, and 55; '324 patent, claims 20 and 31; '657 patent, claim 28; '155 patent, claim 18	"malathion carboxylic acid, including but not limited to O,O-dimethyl-S-(1-carboxy-2-carboxyethoxy) ethyl phosphorodithioate and O,O dimethyl-S-(1-carboxy-2-carboxy) ethyl phosphorodithioate"	"malathion carboxylic acid, including but not limited to: O,O-dimethyl-S-(1-carboxy-2-carboxyethoxy) ethyl phosphorodithioate (i.e., malathion alpha-monocarboxylic acid); O,O-dimethyl-S-(1-carboxyethoxy-2-carboxy) ethyl phosphorodithioate (i.e., malathion beta-monocarboxylic acid); and O,O dimethyl-S-(1-carboxy-2-carboxy) ethyl phosphorodithioate (i.e., malathion dicarboxylic acid)"
"the composition is stable after storage"	'445 patent, claim 35	"the levels of toxic impurities in the composition do not increase significantly"	"the levels of toxic impurities in the composition, other than isomalathion, do not increase significantly after storage; and with respect to the toxic impurity isomalathion, the level in the composition is not more than about 0.1% (w/w): (1) after storage at 5°C for 3 months; (2) after storage at 25°C and 60% RH for 3 months; and (3) after storage at 30°C and 60% RH for 3 months"

"assaying the malathion . . . for the presence of at least one impurity" and "assaying the malathion for purity"	'445 patent, claims 9 and 11; '657 patent, claims 24 and 28	"analyzing a sample of the malathion to determine the amount of at least one impurity by techniques including, but not limited to: (1) high pressure liquid chromatography, (2) gas chromatography, or (3) nuclear magnetic resonance spectroscopy"	"analyzing a sample of the malathion to determine the amount of at least one impurity, wherein the assay is one of: (1) high pressure liquid chromatography, (2) gas chromatography, or (3) nuclear magnetic resonance spectroscopy"
"preparing a solution of O,O-dimethyldithiophosphoric acid"	'445 patent, claim 1; '657 patent, claim 1	"preparing a solution that includes O,O-dimethyldithiophosphoric acid"	"preparing a solution of the free acid form of O,O-dimethyldithiophosphoric acid"

II. LEGAL STANDARD

A. Claim Construction

The claims of a patent define an inventor's right to exclude. *Philips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The court has the exclusive authority to construe patent terms and determine the correct scope of disputed claims as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978-79 (Fed. Cir. 1995). The purpose of claim construction is to objectively determine how a person of ordinary skill in the art would understand a claim at the time of the invention. *Phillips*, 415 F.3d at 1313. In construing a claim, the court may examine both intrinsic evidence (*e.g.*, the patent, its claims, the specification, and the prosecution history) and extrinsic evidence (*e.g.*, expert reports, testimony, and anything else). *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

It is well established that claim construction analysis begins with consideration of the intrinsic evidence. *Id.* Intrinsic evidence is considered "the most significant source of the legally operative meaning of disputed claim language." *Id.* In this regard, the court first looks to the words of the claims themselves. *Id.* Claim terms "are generally given their ordinary and customary meaning." *Id.* However, "a patentee may choose to be his own lexicographer and use

terms in a manner other than their ordinary meaning." *Id.* Therefore, it is important that courts examine other components of the intrinsic evidence to determine whether the patentee has given a term an unconventional meaning. *Id.*

The court should then review the patent specification to determine whether the inventor uses terms inconsistent with their ordinary meaning, or explicitly or implicitly defines terms. *Markman*, 52 F.3d at 979. The specification has long been emphasized as "the single best guide to the meaning of a disputed term" and is usually dispositive in claim construction analyses. *Phillips*, 415 F.3d at 1315. The specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1373 (Fed. Cir. 2001). Indeed, if the specification "reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess," "the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316.

In addition to the claims and specification, the court can consider the patent's prosecution history, which, if in evidence, can inform the meaning of a claim term. *Id*. at 1317. "The prosecution history provides evidence of how the PTO and the inventor understood the patent." *Id.* However, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.*

Finally, a court may consider extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. "However, while extrinsic evidence 'can shed useful light on the relevant art,' . . . it is 'less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Philips*, 415 F.3d. at 1317 (quoting

Vanderlande Indus. Nederland BV v. Int'l Trade Commc'n, 366 F.3d 1311, 1318 (Fed. Cir. 2004)). Extrinsic evidence should therefore be considered only where the intrinsic evidence does not provide a sufficient description to resolve ambiguities in the scope of the claim. *See Vitronics*, 90 F.3d at 1583.

B. Indefiniteness

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). "[D]efiniteness is measured from the viewpoint of a person skilled in [the] art at the time the patent was filed." *Id.* at 908 (citation omitted). "[A] patent must be precise enough to afford clear notice of what is claimed, thereby 'appris[ing] the public of what is still open to them.'" *Id.* at 909 (alteration in original) (citation omitted). At the same time, the definiteness requirement "take[s] into account the inherent limitations of language" and therefore "some modicum of uncertainty" is permitted. *Id.* (citation omitted). Patents are presumptively valid, and to overcome the presumption of validity, an accused infringer must "show[] by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2339 (2011); *Halliburton Energy Sen's., Inc. v. M-I LLC*, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008).

III. DISCUSSION

A. "wherein the sulfur reagent is sodium bisulfite"

The parties dispute the meaning of "wherein the sulfur reagent is sodium bisulfite" found within dependent Claim 7 of the '445 patent and dependent Claim 15 of the '657 patent.

Specifically, the parties disagree as to whether this term limits the contents of the aqueous sulfur solution, or the manner in which the aqueous solution is prepared.

Plaintiffs' proposed construction is "wherein the sulfur reagent is an aqueous solution of sodium bisulfite." This construction limits the contents of the aqueous sulfur solution, but does not limit which compounds can be used to prepare the sodium bisulfite containing aqueous solution. Plaintiffs first argue that their construction is firmly rooted in the specification of the patents-in-suit. They claim that because the specification unequivocally states that the "[t]he acidic, aqueous sulfur solution *may be prepared in any suitable manner*," a person of ordinary skill in art would understand that they were not limited in the manner of preparation of the aqueous solution. *E.g.*, '445 Patent at 7:43-45 (emphasis added). Moreover, Plaintiffs argue that the specification describes what the sulfur solution may be—not what it may be prepared from: "The *sulfur solution may be* for example, a (i) bisulfite . . . ." *E.g.*, '445 Patent at 7:37-43. Finally, Plaintiffs contend that the claim language itself supports the understanding that the "sulfur reagent" refers to the content of the aqueous solution rather than the manner of preparation. Specifically, Plaintiffs note the claims containing the disputed term depend from independent claims covering a process that includes "treating the malathion from stop (c) with sulfur reagent, wherein the sulfur reagent has a pH of less than about 7.0." *E.g.*, '455 Patent, Claim 1. Plaintiffs aver that because pH, a characteristic of a solution, is used to describe the "sulfur reagent" term, "sulfur reagent" must refer to an acidic aqueous solution rather than a method of preparation or intermediary ingredient. Claim 7—containing the disputed term—then narrows the acidic aqueous solution of Claim 1 to an acidic aqueous solution containing sodium bisulfite without mention to how it is prepared.

Defendant asserts that the proper construction of this term is "wherein the sulfur reagent is an aqueous solution prepared from the chemical compound $NaHNO_3$ (i.e., sodium bisulfite)." Defendant contends this construction is supported by the claims read in light of the specification. Specifically, Defendant invokes the disclosure-dedication rule which states that subject matter that is disclosed in a patent but not claimed is dedicated to the public. *Johnson & Johnston Assocs. V. R.E. Serv. Co., Inc.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). Applying the rule to the instant case, Defendant first points out that the specification discloses that the sulfur reagent could be selected from any one of four distinct species within the "bisulfite" genus—sodium bisulfite, sodium metabisulfite, magnesium bisulfite, or ammonium bisulfite. Defendant then argues that because the patent claims recite only one of those distinct species (sodium bisulfite), a person of ordinary skill in the art would understand that the other three species have been dedicated to the public under the disclosure-dedication rule. Because those other species are excluded, Defendant argues the proper understanding of the term is that the sulfur reagent solution must be prepared from the sodium bisulfite compound. Defendant also points out that the specification describes three distinct genuses for making sulfur solutions (bisulfite, sulfite, or sulfide) and the specification expressly indicates that the manner of preparing each solution is different:

> The acidic, aqueous sulfur solution may be prepared in any suitable manner (note, an aqueous solution of a bisulfite is inherently acidic); *suitable methods for preparing an acidic aqueous solution of a bisulfite include dissolving a bisulfite in water*. Aqueous solutions of sulfites or sulfides are inherently basic. Therefore, an acidic, *aqueous solution of a sulfite or sulfide may be prepared by dissolving a sulfite in water followed by an addition of and acid*, ...

E.g., '445 Patent at 7:43-52 (emphasis added). Because of the distinction in the method of preparation amongst the genuses, Defendant argues the manner of preparation is relevant to the construction of the disputed term and a person of skill in the art would interpret it as such.

Defendant also argues that the extrinsic record reinforces its proposed construction. It avers that the Nair reference demonstrates that a person of skill in the art would have known at the time of the invention that the bisulfite species were treated individually. Moreover, it cites the Atkinson reference to show that when different starting material species are used to prepare a solution of sodium bisulfite, the composition of the resulting solution will differ. Defendant argues these references support that their construction is appropriate in light of the prior art.

After reviewing the intrinsic evidence, I reject Defendant's proposed construction, and adopt Plaintiff's construction: "wherein the sulfur reagent is an aqueous solution of sodium bisulfite." The "starting point for any claim construction must be the claims themselves." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298. Here, the disputed claim language states that "the sulfur reagent is sodium bisulfite." Looking at the plain and ordinary meaning of the claim language on its face, there is no indication that the claims themselves refer to the manner or ingredients by which the aqueous sulfur reagent is prepared. Instead, as Plaintiffs point out, the disputed term simply narrows independent Claim 1 which reveals that the "sulfur reagent" is an acidic aqueous solution (because it is defined in terms of a pH characteristic). Because Claim 7 does this without reference to how the solution is prepared, that limitation should not be read into the claims. The plain and ordinary meaning of the claims themselves thus supports construing the term to indicate the contents of the aqueous sulfur solution (containing sodium bisulfite), rather the manner in which it is prepared.

Notwithstanding evidence in the claims themselves, it is necessary to look toward the other intrinsic evidence including the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005). The specification has long been emphasized as "the single best guide to the meaning of a disputed term" and is usually dispositive in a claim construction analysis. *Id.* The

specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1373 (Fed. Cir. 2001). In the instant case, the specification sheds light on the meaning of the disputed term. The specification expressly states that the sulfur solution "*may be for example*, a (i) bisulfite, such as, sodium bisulfite, sodium metabisulfite, magnesium bisulfite or ammonium bisulfite." *E.g.*, '445 Patent at 7:31-39 (emphases added). Moreover, the specification states that "[t]he acidic, aqueous sulfur solution *may be prepared in any suitable manner*." *E.g.*, '445 Patent at 7:46-48 (emphasis added). The use of non-limiting language in both of these instances supports the construction that the aqueous sulfur solution merely contains sodium bisulfite and does not limit the method by which it is prepared (including which compounds are used in its preparation).

Defendant's use of the disclosure-dedication rule in claim construction is inapposite. Indeed, other courts "use the disclosure-dedication rule to limit the scope of the doctrine of equivalents, not to construe the claims in the first instance." *Tawnsaura Grp., LLC v. Maximum Human Performance*, 2013 WL 12139108, at *8 n.5 (C.D. Cal. Aug. 6, 2013); *see also Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1331 (Fed. Cir. 2004) ("The disclosure-dedication rule limits application of the doctrine of equivalents . . . ."). The disclosure-dedication rule is a "logically subsequent determination" to claim construction because applying it during claim construction "would assume the conclusion." *Tawnsaura*, 2013 WL 123139108 at *7-8. Here, by stating that the sodium bisulfite solutions prepared from compounds other than sodium bisulfite are outside the scope of the claims, Defendant assumes that this claim term limits the manner in which the sulfur solution is prepared. This kind of circular reasoning is unpersuasive.

Finally, because the construction is sufficiently clear based on the intrinsic evidence, I decline to consider Defendant's extrinsic evidence. Only where there is some "genuine ambiguity in the claims after consideration of all the available intrinsic evidence" should the court resort to extrinsic evidence in order to construe a claim. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996). Extrinsic evidence is in general "less reliable than the patent and its prosecution history in determining how to read claim terms. . . ." *Philips v. AWH Corp.*, 415 F.3d 1303, 1318 (2005 Fed. Cir.). Extrinsic evidence "is not part of the patent and does not have the specification's virtue of being created at the time of patent prosecution for the purpose of explaining the patent's scope and meaning." *Id.* Moreover, "there is a virtually unbounded universe of potential extrinsic evidence of some marginal relevance that could be brought to bear on any claim construction question." *Id.* Even if the extrinsic evidence here was considered, it would not provide any indication of how a person of skill in the art would understand the claim term in the context of the patents-in-suit. It merely indicates that a person of skill in the art *may* differentiate based on the species used and manner of preparation, but that does not mean the patentee in the instant case intended to do so in its claim. As the meaning of the claim term in the instant case is clear based on the intrinsic evidence, I decline to consider extrinsic evidence for this claim term.[1]

B. "20% sodium bisulfite solution"

The parties dispute the meaning of "20% sodium bisulfite solution" found within Claim 8, 49, and 50 of the '445 patent and Claims 16, 17, and 23 of the '657 Patent. More specifically,

[1] On February 7, 2020, Plaintiffs made a motion to strike Defendant's reliance on two extrinsic evidence references—the Nair and Atkinson reference. The basis for this motion was failure to abide by the New Jersey Local Patent Rules. By resolving this claim construction on the intrinsic evidence alone, Plaintiffs' motion to strike Defendant's extrinsic evidence is moot and need not be considered or addressed.

the parties disagree as to (1) whether Defendant has waived their indefiniteness argument except as to Claim 8 of the '455 Patent, and (2) whether the disputed term is indefinite.

With regard to the first dispute—whether Defendant has waved its indefiniteness argument except as to Claim 8 of the '455 patent—Plaintiffs contend that Defendant is barred from raising indefiniteness for any other claim because Defendant only disclosed an indefiniteness argument for Claim 8 in its Invalidity Contentions. Plaintiff cites *Auxilium Pharm., Inc. v. Watson Labs., Inc.*, No. 12-3084 (JLL), 2014 WL 2624780 (D.N.J. June 12, 2014) to support this proposition, though that case is clearly distinguishable. There, the court denied Defendant's request to amend its Invalidity Contentions to add allegations of indefiniteness where the defendant's Invalidity Contentions lacked *any* allegation of indefiniteness with respect to any claim or term. *Id.* at *1. The question before the court was "whether a party that does not assert indefiniteness [at all] in its invalidity contentions . . . nonetheless can argue during claim construction that certain claim terms are indefinite . . . ." *Id.* at *4. In the case at bar, however, that question is inapt because the disputed term at issue *was* challenged for indefiniteness in the Invalidity Contentions. Although Defendant did not list all claims in which the disputed term appeared in the Invalidity Contention (Defendant failed to indicate the term was also found in Claims 49 and 50 of the '455 patent and Claims 16, 17, and 23 of the '657 patent), Plaintiffs will suffer no prejudice if the indefiniteness argument is applied to Claims 49 and 50 of the '455 patent and Claims 16, 17, and 23 of the '657 patent, because Plaintiffs were on notice of the indefiniteness argument with regard to the exact same claim term in Claim 8 of the '455 at the time of the Invalidity Contentions.

The parties next disagree as to whether the claim term, "20% sodium bisulfite solution," is indefinite. Defendant contends the claim term is indefinite because (1) it lacks an antecedent

basis and (2) there is no reasonable certainty as to the correct unit of measure of concentration for "20%." Defendant argues the term here lacks an antecedent basis because there is "no earlier recitation or limitation" of the term, and it is "unclear as to what element the [term] was making reference." *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1343 (Fed. Cir. 2008) (citation omitted). Specifically, it avers the claim statement "treatment with *the* 20% sodium bisulfite solution" could refer to any step before it, or even an unstated step. *E.g.*, '455 Patent, Claim 8. Defendant asserts that because the patent lacks an antecedent basis that can be ascertained with any reasonable certainty, "competitors cannot avoid infringement" of the claim and it must be found invalid. *Halliburton Energy Serv., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008). Defendant also argues a person of skill in the art would not be able to determine from the specification or claims with reasonable certainty the unit of measurement for the "20%" in the claim term. Defendant argues that because there are multiple well-accepted ways to express solution concentration, and the specification employs both weight-per-weight (w/w) and volume-per-volume (v/v) measures of concentration for various solutions, a person of skill in the art would not be certain which unit of measure was intended. Defendant therefore argues the claim must be found invalid.

Plaintiffs assert the term is not indefinite and the plain and ordinary meaning of the term read in context of the claim and specification as a whole is: "a solution that includes 20% (w/w) sodium bisulfite." Plaintiffs contend the patent claim is not indefinite for lack of antecedent basis because the specification of the patent makes clear what "*the* 20% sodium bisulfite solution" refers to the "sulfur reagent" disclosed in step (d) of Claim 1. *E.g.*, '455 Patent, Claim 1, 8. Second, Plaintiffs argue that a person of skill in the art reading the terms in light of the claim language and specification would readily understand that the unit of measure of the 20%

sodium bisulfite solution is weight-per-weight (w/w) because there are multiple instances in the specification in which the (w/w) measure of concentration is used to describe the 20% sodium bisulfite solution. Moreover, no other unit of measure is used to describe the 20% sodium bisulfite solution in the entire intrinsic record. Therefore, Plaintiffs argue a person of skill in the art would not be uncertain as to the unit of measure for this term.

I construe the "20% sodium bisulfite solution term" to match Plaintiff's construction: "a solution that includes 20% (w/w) sodium bisulfite." Contrary to Defendant's assertions, the disputed term here does not lack an antecedent basis based on a reading of the claim in light of the specification. A person of skill in the art would read Claim 8—containing the term—in light of the specification of the '445 patent, which states:

> In one embodiment, *the sulfur reagent is sodium bisulfite*. In another embodiment the sulfur reagent comprises a 20% sodium bisulfite solution having a pH from about 6.1 to about 6.3. The malathion in step (d) may be treated with *the 20% sodium bisulfite solution* for about 2 hours. *After treatment with the 20% sodium bisulfite solution, the malathion may be washed with water*. . . .

'445 Patent at 3:53-61 (emphasis added). The specification clearly defines "the sulfur reagent" as a "20% sodium bisulfite solution." It then clarifies the relationship between Claim 8 and Claim 1, explaining that "the malathion in step (d) may be treated with the 20% sodium bisulfite solution" and then "after treatment with the 20% sodium bisulfite solution, the malathion may be washed with water." *Id.* at 3:57-60. In light of this language in the specification, a person of skill in the art would be reasonably certain that the "20% sodium bisulfite solution" disclosed in step (e) of dependent Claim 8 is the "sulfur reagent" disclosed in step (d) of independent Claim 1. Thus, it is not "unclear as to what element the [term is] making reference" and the claims using the disputed term are valid. *Baldwin*, 512 F.3d at 1343.

A patent is indefinite "if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 878, 901 (2014). "Notably, a claim is indefinite if its language 'might mean several different things and no informed and confident choice is available among the contending definitions." *Media Rights Techs., Inc. v. Capital Fin. Corp.*, 800 F.3d 1366, 1371 (quoting *Nautilus*, 572 U.S. at 911 n.8). In the instant case, it is undisputed that the claim itself provides no unit of measure for the "20% sodium bisulfite solution" term. Notwithstanding this, a person of skill in the art would look to the specification to ascertain the term's unit of measure. In at least one portion in the specification the "20% sodium bisulfite solution" term clearly and consistently uses the (w/w) unit of measure in conjunction with the disputed term:

> In one embodiment, the diethyl maleate, which contains malathion is treated with a 20% *(w/w)* solution of sodium bisulfite (pH from about 6.1 to about 6.3). After mixing the diethyl maleate with the 20% *(w/w)* sodium bisulfite solution at about 60°C for about 2 hours, the mixture containing the two solutions, diethyl maleate and 20% *(w/w)* sodium bisulfite is cooled . . . .

E.g., '455 patent at 8:1-7 (emphases added). Though three other instances of the claim term throughout the specification fail to include any unit of measure, a person of skill in the art would determine with reasonable certainty that the correct unit of measure is "(w/w)". This is because no other unit of measure is used in conjunction with the 20% sodium bisulfite solution term throughout the entire intrinsic record. Moreover, other units of measure such as "(v/v)" appear only in a portion of the specification describing concentrations of solutions of distinctly different chemicals, such as hydrogen peroxide. Since "(w/w)" is the only unit referenced in connection with the sodium bisulfite solution, a person of skill in the art would not need to choose amongst "contending definitions" for the unit of measure. *See Media Rights Techs.*, 800 F.3d at 1371.

Finally, the case raised by Defendant, *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1344-45 (Fed. Cir. 2105), is distinguishable from the instant case. In *Teva*, the Federal Circuit found that the disputed term "molecular weight" was indefinite because the unit of measure could not be ascertained from three possible measures. *Id.* The claims and specification there did not provide any indication of which measure should be used. *Id.* This differs substantially from the case at bar in which the only one unit of measure is associated with the disputed term in the intrinsic evidence.

C. "malathion carboxylic acid[s]"

Prior to a concession at the *Markman* hearing, the parties had disputed the meaning of "malathion carboxylic acid[s]" found within Claims 1, 11-12, 32-34, and 53 of the '445 patent, Claims 20, and 31 of the '324 patent, Claim 28 of the '657 patent, and Claim 18 of the '155 patent. Although both parties agreed the claim term was non-limiting (open-ended to include the possibility of multiple chemical species), the parties disagreed as to which exemplary species of "malathion carboxylic acid[s]" should actually be stated as exemplary species in the construction of the disputed patent claim term.

The most relevant portion of the specification of the patents-in-suit provided the description of the "malathion carboxylic acid[s]" term, reciting: "[M]alathion carboxylic acids such as O,O-dimethyl-S-(1-carboxy-2-carboxyethoxy) ethyl phosphorodithioate or O,O-dimethyl-S-(1-carboxy-2-carboxy) ethyl phoshorodithioate." *E.g.*, '445 Patent at 9:47-50. The two exemplary species listed there are commonly referred to as "malathion alpha-monocarboxylic acid" and "malathion dicarboxylic acid," respectively. Plaintiffs contended that in addition to non-limiting claim language, only those two species should be stated as exemplary species in the construction since they were the only species explicitly listed in the intrinsic evidence. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 811 (Fed. Cir. 2002)

("'such as' introduces an example of a broader genus rather than limiting the genus to the exemplary species."). Plaintiffs therefore adopted a construction which directly mirrored the language of the specification: "malathion carboxylic acids, including but not limited to O,O-dimethyl-S-(1-carboxy-2-carboxyethoxy) ethyl phosphorodithioate and O,O-dimethyl-S-(1-carboxy-2-carboxy) ethyl phoshorodithioate."

Defendant had contended that extrinsic evidence demonstrated that a person of skill in the art would be aware of a third exemplary species, "malathion beta mono-carboxylic acid." Therefore, Defendant proposed a similar construction to Plaintiffs, but listed an additional exemplary species, "malathion beta mono-carboxylic acid," in its construction: "malathaion carboxylic acid, including but not limited to: O,O-dimethyl-S-(1-carboxy-2-carboxyethoxy) ethyl phosphorodithioate (i.e., malathion alpha-monocarboxylic acid); O,O-dimethyl-S-(1-carboxyethoxy-2-carboxy) ethyl phosphorodithioate (i.e., malathion beta-monocarboxylic acid); and O,O dimethyl-S-(1-carboxy-2-carboxy) ethyl phosphorodithioate (i.e., malathion dicarboxylic acid)."

At the *Markman* hearing on February 19, 2020, Defendant agreed to adopt Plaintiffs' construction of this disputed term if Plaintiffs conceded that their construction did not suggest "beta mono-carboxylic acid" was excluded as a potential malathion carboxylic acid under the non-limiting language in the construction. *Markman* Hearing Transcript at 51:7-19. Plaintiffs made the concession. *Id.* As a result of this, and the fact that Plaintiffs' construction is directly supported by the intrinsic record, I adopt Plaintiffs' construction for this disputed term: "malathion carboxylic acids, including but not limited to O,O-dimethyl-S-(1-carboxy-2-carboxyethoxy) ethyl phosphorodithioate and O,O-dimethyl-S-(1-carboxy-2-carboxy) ethyl phoshorodithioate." I would like to make clear that this does not mean "beta mono-carboxylic

acid" is a carboxylic acid within the meaning of this claim term. This means only that "beta mono-carboxylic acid" is not excluded from being contained within the non-limiting claim language. If the parties later dispute whether "malathion beta mono-carboxylic acid" is covered by this construction, it will be an issue for expert discovery.

D. "the composition is stable after storage"

The parties dispute the meaning of "the composition is stable after storage" found within Claim 35 of the '445 patent. The parties disagree as to whether this term includes a set of specific stability limitations for isomalathion found within the specification.

Plaintiffs' proposed construction for this term is "the levels of toxic impurities in the composition do not increase significantly." Plaintiffs argue their construction is based on the language of the specification of the patents-in-suit, which states: "The malathion of the present invention *is stable after storage, i.e.*, even after storage at elevated levels of temperature and humidity, *the levels of toxic impurities do not increase significantly*." *E.g.*, '445 patent at 2:67-3:3 (emphasis added).

Defendant's proposed construction incorporates the same language used in Plaintiffs' construction, but it also argues an additional limitation should be imported for isomalathion due to other language found within the specification:

> The malathion prepared by the process of this invention is *stable after storage. Specifically*, after storage at 5°C. for 3 months the amount of isomalathaion is not more than about 0.1% (w/w). After storage for 3 months at 25°C. and 60% relative humidity ["RH"], the amount of isomalathion is not more than about 0.1% (w/w). After storage for 3 months at 30°C. and 60% relative humidity, the amount of isomalathion is not more than about 0.1% (w/w).

E.g., '455 Patent at 4:48-56 (emphasis added). Defendant argues that the patentee's use of the word "specifically" in this section of specification shows an unequivocal intention to define the "stable after storage" term with a quantifiable limit on the amount of isomalathion that can be

present after storage for three months under each of the three listed storage conditions. Thus, Defendant contends the proper construction of this term is "the levels of toxic impurities in the composition, other than isomalathion, do not increase significantly after storage; and with respect to the toxic impurity isomalathion, the level in the composition is not more than about 0.1% (w/w): (1) after storage at 5°C for 3 months; (2) after storage at 25°C and 60% RH for 3 months; and (3) after storage at 30°C and 60% RH for 3 months."

I construe "the composition is stable after storage" term to match Plaintiff's construction: "the levels of toxic impurities in the composition do not increase significantly." A patent applicant can act as its own lexicographer in providing an explicit definition in the specification for a claim term, however the patentee's lexicography must appear "'with reasonable clarity, deliberateness, and precision' before it can affect the claim." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998) (quoting *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994)). In the instant case, Defendant's construction at first glance does have some merit because the specification uses the word "specifically" to indicate that the definition of the claim term includes quantifiable limits on the amount of isomalathion that can be present after storage for three months under each of three storage conditions. '455 Patent at 4:48-56 (emphasis added). However, as Plaintiff points out, this definitional language is undermined by another portion of the specification which states "[s]tability may be characterized by the fact that levels of isomalathion . . . *do not exceed 0.2% (w/w)* after storage." *E.g.*, '455 Patent at 165-9 (emphasis added). Given the inconsistency between the two portions of the specification regarding the stability claim term, a person of skill in the art would not be reasonably certain of the patentee's intent with regard to the maximum level of isomalathion for

stability.[2] Indeed, the patentee's lexicography does not appear "with reasonable clarity, deliberateness, and precision and should therefore not affect the claim." *See Renishaw*, 158 F.3d at 1249. Since no consistent definition is provided in the intrinsic evidence with regard to a quantifiable limitation for isomalathion, it would not be clear to any person of skill in the art that Defendant's limitation would be found within the construction of this term. Because Plaintiffs' construction is fully supported by the plain and ordinary meaning of the intrinsic evidence, it is adopted.

E. "assaying the malathion . . . for presence of at least one impurity" and "assaying the malathion for purity"

The parties dispute the meaning of "assaying the malathion . . . for presence of at least one impurity" and "assaying the malathion for purity" found within Claim 9 and 11 of the '445 patent and Claims 24 and 28 of the '657 patent. The parties disagree as to whether these terms are limited to the three assay techniques expressly disclosed within the intrinsic evidence or are non-limiting and open to other techniques.

Plaintiffs' proposed construction for this term is "analyzing a sample of the malathion to determine the amount of at least one impurity by techniques including, but not limited to: (1) high pressure liquid chromatography, (2) gas chromatography, or (3) nuclear magnetic resonance spectroscopy." Plaintiffs argue that nothing in the claim language limits the techniques by which malathion can be assayed. Plaintiffs contend their construction is proper based on the language of a relevant portion of the specification of the patents-in-suit, which states:

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[2] One portion of the specification indicates stability is demonstrated when isomalathion does not exceed 0.1% (w/w), while another portion indicates stability may be achieved if isomalathion does not exceed 0.2% (w/w). Therefore it is not clear from the specification which maximum level of isomalathion is indicative of stability. In the case that a person of skill in the art measured 0.15% isomalathion, the sample tested could be found to be stable or unstable depending on which level of maximum isomalathion was adopted.

> [T]he purity of the malathion may be assayed by high pressure liquid chromatography (HPLC). Other techniques for assaying the purity of malathion and for determining the presence of impurities *include*, gas chromatography (GC), and nuclear magnetic resonance (NMR) spectroscopy.

E.g., '445 Patent at 8:14-19 (emphasis added). Plaintiffs argue that this portion of the specification reveals that the disputed term is not limited to the techniques listed in the specification. In support, Plaintiffs cite *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293 (Fed. Cir. 2006), a case in which the Federal Circuit held the use of the word "included" in the specification was non-limiting.

Defendant argues that the term is limited to the three assay techniques explicitly identified in the specification (HPLC, GC, NMR). Thus, Defendant's proposed construction for this term is "analyzing a sample of the malathion for purity, wherein the assay is one of: (1) high pressure liquid chromatography, (2) gas chromatography, or (3) nuclear magnetic resonance spectroscopy." In coming to its proposed construction, Defendant relies extensively on *Honeywell Int'l, Inc. v. ITC*, 341 F.3d 1332 (Fed. Cir. 2003). In that case, the intrinsic evidence did not disclose the sample preparation method necessary to produce PET yarn with certain mechanical properties in a process patent. *Honeywell*, 341 F.3d at 1334-36. There, the court found that that the preparation method was critical to both practice and discern the bounds of the invention, and it therefore found the claims indefinite. *Id.* at 1340. In the instant case, Defendant argues that the intrinsic evidence of the patents-in-suit makes clear that reduction of impurities is the heart of the patentee's purported invention. Defendant argues that the proper assay is therefore critical to practice this invention and construction should be construed narrowly and limited to only those techniques expressly listed in the intrinsic evidence.

I construe "assaying the malathion . . . for presence of at least one impurity" and "assaying the malathion for purity" to match Plaintiff's construction: "analyzing a sample of the

malathion to determine the amount of at least one impurity by techniques including, but not limited to: (1) high pressure liquid chromatography, (2) gas chromatography, or (3) nuclear magnetic resonance spectroscopy." As Plaintiffs note, the language of the claims themselves does not limit the techniques by which malathion can be assayed. Moreover, under *Amgen*, the use of the word "including" in the specification indicates the disputed claim term would be interpreted by a person of skill in the art as non-limiting. Defendant is unable to offer a persuasive argument as to why *Amgen* would not apply, and Defendant's reliance on *Honeywell* is inapposite. *Honeywell* is distinguishable because it is a case in which the Federal Circuit found all claims of the asserted patent indefinite because the patent failed to provide any guidance as to critical method of sample preparation. In the instant case, not only has indefiniteness not been asserted for the claim term in question, but the intrinsic record provides clear guidance to a person of skill in the art on at least three acceptable assay techniques. Furthermore, in *Honeywell*, the determination that the sample method was "critical" to discerning infringement was based on a factual finding that the manner in which a sample of PET yarn was prepared for testing materially affected the results of the test, which in turn impacted infringement. *Id.* at 1336. Here, although Defendant has indicated that Plaintiffs' "WHO Pharmaceutical Preparations" treatise reveals certain flaws with assay techniques not disclosed in the intrinsic evidence, there is no explicit indication that they produce materially different results in calculating the purity of malathion. Taro, Ex. 10, *WHO Expert Committee on Specifications for Pharmaceutical Preparations,* WHO TECHNICAL REPORT SERIES, 35th Report (1999). Finally, Defendant's own references disclose additional assay techniques for determining the purity and impurity content of malathion. Novitium Ex. F, Bourquin, at NOV-OVIDE_00004851-55 (disclosing the use of thin layer chromatography (TLC) to analyze purity

and metabolite content of malathion); Novitium Ex. F., Bourquin, at NOV-OVIDE_00004851-55 (discussing the use of TLC and IR spectroscopy).[3] Although these assaying methods may not appear in the same context as the invention (pharmaceutical anti-lice treatment), they are used in assaying the same compound, malathion. Thus, a person of skill in the art would have knowledge of them at the time of the invention. Accordingly, Defendant's arguments based on *Honeywell* do not support narrowly construing the "assaying the malathion" terms in a manner that is contrary to the clear, open ended language of the specification.

F. "preparing a solution of O,O-dimethyldithiophosphoric acid"

The parties dispute the meaning of "preparing a solution of O,O-dimethyldithiophosphoric acid" found within Claim 1 of the '445 patent and Claim 1 of the '657 patent. The parties disagree as to whether this term requires preparation using the free acid form of O,O-dimethyldithiophosophoric acid ("OODPA").

Defendant argues the plain and ordinary meaning of the term in light of the intrinsic evidence is "preparing a solution of the free acid form of O,O-dimethyldithiophosphoric acid." Defendant contends that the claims themselves suggest preparing the free acid form—as opposed to a salt form—of OODPA: "preparing a solution of O,O-dimethyldithiophosphoric *acid* . . . in an organic solvent . . . ." *E.g.*, '445 Patent, Claim 1 (emphasis added). Furthermore, Defendant points to additional intrinsic evidence to prove that the patentees intended for OODPA to mean "acid" rather than "salt." Specifically, Defendants cite Provisional Patent Application No. 60/697,010 (the '010 provisional") which led to the patents-in-suit, as well as Patent No.

[3] Although Plaintiffs argue that their extrinsic evidence reference by the World Health Organization (WHO) recognized acceptable assay techniques for purity outside the three expressly listed in the patents-in-suit, these references did not state those assay techniques were suitable for measurement of malathion purity. *See* Taro, Ex. 10, *WHO Expert Committee on Specifications for Pharmaceutical Preparations*, WHO Technical Report Series, 35th Report (1999) at 34-38. The WHO reference therefore neither supports nor defeats Plaintiff's proposed construction.

4,049,755 ("the '755 patent"), which is incorporated by reference in its entirety by the '445 and '657 Patents. The '010 provisional notes that sodium salts of OODPA are "not suitable for preparing malathion" because such forms are "unreactive towards diethyl maleate." U.S. Provisional Patent App. No. 60/697,010 at 2:9-10. The '755 patent distinguishes between OODPA and "salts of said acid," noting that OODPA "is an intermediate for the preparation of . . . malathion," while the salts are "used as starting martials for . . . insecticides, such as, dimethoate . . . ." '755 Patent at 1:7-16.[4]

Plaintiffs argue the plain and ordinary meaning of the term would be clear to a person of skill in the art in light of the specification. Plaintiffs argue that there is no definitional language in the specification or file histories of the patents-in-suit or disclaimers that act to limit the claims to processes that prepare only free acid form of OODPA. Thus, Plaintiff's construction is "preparing a solution that includes O,O-dimethyldithiophosphoric acid."

I construe "preparing a solution of O,O-dimethyldithiophosphoric acid" to match Defendant's construction: "preparing a solution of the free acid form of O,O-dimethyldithiophosphoric acid." The intrinsic evidence cited by Defendant reveals that OODPA has clearly been distinguished from "salts of said acid." It provides evidence that one form (salt form) is disparaged in favor of another (free acid form). Finally, Plaintiffs are unable to cite any

[4] Plaintiffs contend that Defendant has violated Local Patent Rules 4.2 and 4.3 through its use of the '755 Patent which was not disclosed as evidence prior to its opening brief. Plaintiffs argue that the evidence should therefore be excluded. L. PAT. R. 4.3(b) (requiring "an identification of all references from the intrinsic evidence that support [a party's] construction"). While it is apparent that Defendant has violated these rules, the Local Patent Rules are silent on the remedy to be applied. While I find the Defendant's conduct unacceptable, Plaintiff has not been prejudiced to such an extent that warrants exclusion of the intrinsic evidence. Certainly Plaintiffs cannot argue they were not aware of the intrinsic evidence—the patents and their prosecution history—since the beginning of the case. *See Sightsound Techs., LLC v. Apple, Inc.*, 2012 WL 12896175, at *4 (W.D. Pa. Nov. 19, 2012) ("[Defendant] has not been prejudiced [by violation of Local Patent rule 4.2] to such an extent that warrants exclusion of the intrinsic evidence."); *Janssen Products, L.P. v. Lupin Ltd.*, Civ. No. 10-5954 (WHW), 2013 WL 3772655, at *4 (D.N.J. July 16, 2013) ("Recognizing that motions to strike are disfavored and usually denied, and considering Plaintiffs' failure to demonstrate that this case is in any way exceptional, the motion to strike portions of Defendants' responsive *Markman* is denied.")

portions of the specification and claims of the patents-in-suit that indicate that any material but the free acid form of OODPA should be used in preparation of the solution. Plaintiffs are also unable to point to any language in the intrinsic evidence to justify their broad construction. *See Novartis Pharm Corp. v. Wockhardt USA LLC*, C.A. No. 12-cv-3967 (SDW)(MCA), 2014 WL 2861209 (D.N.J. June 24, 2014) (rejecting patentee's broad construction where there was no indication from the claim language that a certain material "was intended to be merely a component of the bag's materials"). Therefore, Defendant's construction using the free acid form of OODPA is correct.

IV. CONCLUSION

In light of the foregoing reasons, the Court construes the disputed claim terms as represented in the chart below:

Disputed Claim Terms	**Constructions**
"wherein the sulfur reagent is sodium bisulfite"	"wherein the sulfur reagent is an aqueous solution of sodium bisulfite"
"20% sodium bisulfite solution"	"a solution that includes 20% (w/w) sodium bisulfite"
"malathion carboxylic acid[s]"	"malathion carboxylic acid, including but not limited to O,O-dimethyl-S-(1-carboxy-2-carboxyethoxy) ethyl phosphorodithioate and O,O dimethyl-S-(1-carboxy-2-carboxy) ethyl phosphorodithioate"
"the composition is stable after storage"	"the levels of toxic impurities in the composition do not increase significantly"
"assaying the malathion . . . for the presence of at least one impurity" and "assaying the malathion for purity"	"analyzing a sample of the malathion to determine the amount of at least one impurity by techniques including, but not limited to: (1) high pressure liquid chromatography, (2) gas chromatography, or (3) nuclear magnetic resonance spectroscopy"
"preparing a solution of O,O-dimethyldithiophosphoric acid"	"preparing a solution of the free acid form of O,O-dimethyldithiophosphoric acid"

DATED: April 6, 2020

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson
U.S. Chief District Judge